US ERA ARCHIVE DOCUMENT

DICLORAN TECHNICAL

EPA Primary Reviewer: P. V. Shah, Ph.D. Registration Action Branch 1/HED (7509C) Dermal Sensitization Study (§81-6) PV Shuh 3/15/01

EPA Secondary Reviewer: William Dykstra, Ph.D. Registration Action Branch 1/HED (7509C)

W/ Captition 3 / 20/01

DATA EVALUATION RECORD- SUPPLEMENTAL See TXR No. 002624 for Original DER

NOTE:

This study was previously reviewed and classified as Minimum. However, the format for the executive summary and the first page of the DER were different from the current format. This is to update the format and, at the same time, to add needed data to the DER for the ease of evaluating this study.

STUDY TYPE: Dermal Sensitization - Guinea pig

OPPTS Number: 870.2600

OPP Guideline Number: §81-6

DP BARCODE: D241078

SUBMISSION NO.: S541375

PC CODE 031301

TOX. CHEM. NO.: 311

MRID NO: 00082721

TEST MATERIAL (PURITY): Dicloran Technical (Purity not specified)

COMPOSITION/SYNONYM(S): 2,6-dichloro-4-nitroaniline; DCNA; BotranTM

CITATION:

Johnson, R. L., and Schwikert, R. S. (1963) Letter sent to E. S. Feenstra dated Feb 21, 1963. U02069: 2, 6-dichloro-4-nitroaniline or Botran: Skin Sensitization in Guinea Pigs. Reference No. 5567-64-RLJ-106B. February 21, 1963. MRID Number 00082721. Unpublished.

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The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 00082721) conducted with dicloran technical(purity not specified) 10 male guinea pigs were tested for sensitization. Dicloran suspension (0.1% in sodium chloride) was injected intracutaneously (0.1 mL suspension) every other day until a total of 10 had been made. First injection was of 0.05 mL. The challenge injection of 0.05 ml was applied 2 weeks after.

The average sensitization result of the challenge injections was higher than the average of the induction injections. Based on the results of this study, dicloran technical is a potential skin sensitizer.

This study is classified as acceptable (§81-6) and satisfies the guideline requirement for a dermal

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Dermal Sensitization Study (§81-6)

sensitization study in the guinea pig. This study does not meet the current guideline requirements, however, it is classified as acceptable/guideline study because the results of the study indicate that the test compound is a potential skin sensitizer. Therefore, the repeat test is not likely change the results and its Toxicity Category.